

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S. LLC, et al.,

Plaintiffs,

v.

**BRECKENRIDGE PHARMACEUTICAL,
INC.,**

Defendant.

Civil Action Nos. 15-289 (MAS)(LHG)
15-1836 (MAS)(LHG)

MEMORANDUM OPINION & ORDER

Presently before the Court is a dispute as to the terms of a proposed Discovery Confidentiality Order (“DCO”). The parties submitted a joint letter to the Court seeking entry of a DCO to which they have agreed with the exception of one issue: the scope of the access to certain highly confidential materials that will be conferred upon one in-house attorney for Defendant Breckenridge Pharmaceutical, Inc. (“Breckenridge”). Letter of July 16, 2015 (“Joint Letter”) [Docket Entry No. 41].¹

Pursuant to Fed. R. Civ. P. 78, the Court has reviewed the submission of the parties without oral argument. For the reasons set forth below, Breckenridge Pharmaceutical’s request that their in-house attorney be permitted access to outside-counsel-only documents is hereby GRANTED, with certain limitations as set forth below.

I. BACKGROUND

This dispute is one of many moving parts to a complex whole. To date, Plaintiff Sanofi-Aventis U.S. LLC (“Sanofi”) has filed at least sixteen separate suits against nine defendants,

¹ Docket Entry Number references are to the 15-cv-289 docket.

alleging infringement of three patents directed to the anti-prostate-cancer drug, JEV TANA®. In the two captioned suits against Breckenridge, the parties have submitted a proposed DCO [Docket Entry No. 41 pp. 9-33], to which the parties have jointly stipulated, with the exception of the access to highly confidential documents that will be permitted for Breckenridge's in-house counsel, Robert Vroom, Esq. ("Vroom"). The DCO provides for two designation levels for protected discovery materials: "CONFIDENTIAL" and "HIGHLY CONFIDENTIAL, OUTSIDE COUNSEL EYES ONLY." DCO at ¶¶ 6–8. The parties agree that Vroom may have access to materials marked "CONFIDENTIAL," but disagree as to his access to the higher-tier materials marked "HIGHLY CONFIDENTIAL, OUTSIDE COUNSEL EYES ONLY."

II. THE PARTIES' POSITIONS

A. Breckenridge's Arguments

Breckenridge's portion of the joint letter is supported by a declaration from Vroom himself ("Vroom Dec.") [Docket Entry 41-2] and argues that it specifically created the position of Litigation Counsel so that one of its in-house attorneys could function as an outside attorney. Joint Letter at 1; Vroom Dec. ¶ 7. To that end, Vroom does not engage in competitive decisionmaking at Breckenridge; in fact he is ethically walled off from all competitive decisionmaking. Joint Letter at 1; Vroom Dec. ¶ 1. Specifically, he is "not involved in pricing, product design, patent prosecution, or deciding [for] which brand-name drug products Breckenridge will submit ANDA applications" nor is he "involved in determining which companies Breckenridge will partner with." Vroom Dec. ¶ 4. Moreover, Breckenridge's proposed DCO would bar Vroom from engaging in these and similar activities during this litigation and for one year thereafter. Vroom Dec. ¶ 5; DCO p. 11.

Vroom works chiefly from home or from the offices of Breckenridge's outside counsel in Washington, D.C. and Virginia, although he concedes that he does work approximately fifteen days per year at a Breckenridge corporate office in New York shared by Breckenridge's other three in-house counsel. Vroom Dec. ¶ 8. Vroom does not have access to Breckenridge's networked drives, nor does Breckenridge have access to Vroom's computer or his drives. Vroom Dec. ¶ 9.

Breckenridge cites authority from the Court of Appeals for the Federal Circuit and other districts that have permitted in-house counsel full access to confidential materials. Joint Letter at 2. This line of cases follows guidance from the Federal Circuit in *U.S. Steel Corp., et al. v. United States*, 730 F.2d 1465 (Fed. Cir. 1984), which held that the in-house status of counsel "cannot alone create [a] probability of serious risk to confidentiality and cannot therefore serve as the sole basis for denial of access." *Id.* at 1469. Rather, a case-by-case and attorney-by-attorney inquiry should be performed as to whether an in-house counsel engages in competitive decisionmaking that might pose a risk of inadvertent disclosure of protected information. *See id.* As noted above, Breckenridge asserts that Vroom engages in no such competitive decisionmaking. Breckenridge also argues that it would suffer significant harm if it were effectively deprived of Vroom's counsel should Vroom be barred from reviewing the full breadth of discovery materials.

Breckenridge also notes that Plaintiff offered to allow Vroom full access if similar access were granted to Plaintiffs' in-house counsel, with some restrictions. According to Breckenridge, this belies any real concern as to the protection of information if Vroom is given full access. Joint Letter at n.2.

Finally, Breckenridge opposes Sanofi's various procedural arguments. It disagrees with Sanofi's position that the Court should enter the form DCO provided by the Local Rules because the parties were unable to reach agreement. *Id.* at 3. It likewise rejects Sanofi's argument that Breckenridge bears the burden of showing good cause for adding an exclusion to the DCO for Vroom. Rather, Breckenridge argues, Sanofi should have to shoulder that burden because it is attempting to add an additional restriction. *Id.* Breckenridge also disputes the relevance of Sanofi's invocation of New Jersey and New York Court Rules for the proposition that Vroom cannot practice as part of Breckenridge's trial team.

B. Sanofi's Arguments

In a single paragraph, Sanofi argues that full disclosure to Vroom poses a serious risk because Breckenridge is a small company and its four in-house lawyers work as a team. Joint Letter at 6. Also, Breckenridge's reporting structure is problematic insofar as Vroom reports directly to the general counsel, who also serves as Vice President of Corporate Strategy. *Id.* Sanofi also contends that disclosing information about non-cabazitaxel products to Vroom poses a specific risk because Breckenridge files generic applications for pharmaceutical products both for itself and for its potential partners. *Id.* Sanofi also points to Vroom's history of negotiating settlement agreements for Breckenridge and argues that granting him access to Sanofi's sensitive financial information will give Breckenridge a competitive advantage in future settlement agreements. *Id.*

Sanofi contends that Breckenridge would suffer no prejudice if Vroom is denied full access to discovery. It rejects Breckenridge's argument that Vroom needs full access to perform his role as speculative at best. *Id.* In particular, Sanofi argues that Breckenridge has failed to adequately explain why Vroom needs access to highly sensitive business planning and financial

information. *Id.* In addition, Breckenridge has hired two outside law firms to represent it, one of which is among the 100 largest firms in the country. *Id.*

Sanofi distinguishes the majority of the cases cited by Breckenridge on the basis that they dealt with single-tiered DCO's, effectively presenting those courts with a more problematic all-or-nothing decision. Joint Letter at 4. Here, by contrast, the only dispute is whether Vroom may access a narrow subset of the most closely-guarded documents: (1) sensitive financial or business information and future marketing plans and forecasts; (2) processes; and (3) information about non-cabazitaxel products. *Id.* Sanofi separately distinguishes each of the cases cited by Breckenridge that do address two-tiered DCO's. Sanofi points out that the court in *Intervet, Inc. v. Merial Ltd.*, 241 F.R.D. 55 (D.D.C. 2007), granted access to highly confidential documents to in-house counsel who had asserted that she had an expertise that outside counsel did not share. 241 F.R.D. at 56. By contrast, Vroom makes no such claim of special expertise. According to Sanofi, *Sprint Communications Co. L.P. v. Big River Telephone Company, LLC*, Civ. No. 08-2046, 2008 WL 4401690 (D. Kan. Sept. 16, 2008), is also distinguishable because the in-house counsel in that case worked exclusively in the party's litigation department. 2008 WL 4401690, at *3.

In support of its position, Sanofi directs the Court's attention to two decisions which denied in-house counsel access to confidential documents: *Intel Corp. v. VIA Technologies, Inc.*, 198 F.R.D. 525, 530 (N.D. Cal. 2000), and *Inter-Med Inc. v. ASI Medical Inc.*, Civ. No. 09-383, 2010 WL 2679992 (E.D. Wis. July 1, 2010). *Id.* at 5.

Sanofi further argues that New Jersey Court Rule 1:27-2 (a) & (d) and New York Codes, Rules, and Regulations 522.4(b) prohibit Vroom from acting as outside counsel. *Id.* at 5. It also

points to the Local Patent Rules, which distinguish between in-house and outside counsel in the context of a DCO. *Id.*

Finally, Sanofi responds that it was willing to compromise the issue by way of a side agreement, but that agreement would have had additional restrictions. Joint Letter at n.4. Sanofi does not indicate what those restrictions were.

III. STANDARD

The Third Circuit² has yet to opine as to the standard for determining whether in-house counsel should be permitted access to materials designated confidential under a DCO. In the absence of Third Circuit authority, courts in this circuit have looked to guidance provided by the Federal Circuit in *U.S. Steel Corp. v. United States*, 730 F.2d 1465 (Fed Cir. 1984) (“*U.S. Steel*”). See, e.g., *Warner Chilcott Laboratories Ireland Ltd. v. Impax Labs., Inc.*, Civ. No. 08-6304, 2009 WL 36227947, at *2 (D.N.J. Oct. 29, 2009) (“*Warner Chilcott*”); *Affymetrix, Inc. v. Illumina, Inc.*, Civ. No. 04-901, 2005 WL 1801683, at *2 (D. Del. July 28, 2005); *Carpenter Tech. Corp. v. Armco, Inc.*, 132 F.R.D. 24, 27 (E.D. Pa. 1990).

In *U.S. Steel*, the Federal Circuit held that an attorney’s “status as in-house counsel cannot create the probability of serious risk to confidentiality and cannot therefore serve as the sole basis for denial of access.” 730 F.2d at 1469. Rather, courts are to conduct a two-step analysis. First, courts are to assess “[w]hether an unacceptable opportunity for inadvertent disclosure exists.” *Id.* For the purposes of that assessment, the Federal Circuit observed that a court may consider an attorney’s involvement in “competitive decisionmaking” as a serviceable

² While the parties do not brief a choice of law issue, their submissions center on decisions from the Court of Appeals for the Federal Circuit. The Court recognizes that, generally speaking, Federal Circuit law controls matters that implicate substantive patent law, while routine discovery disputes such as this one are controlled by the law of the regional circuit. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803 (Fed. Cir. 2000).

shorthand. *Id.* at 1468 n.3. The Federal Circuit described competitive decisionmaking as “input into pricing, product design, etc.” *Id.*

Second, a court “must balance [risk of disclosure] against the potential harm to the opposing party from restrictions imposed on that party’s right to have the benefit of counsel of its choice.” *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1380 (Fed. Cir. 2010) (citing *U.S. Steel*, 730 F.3d at 1468). “In balancing these conflicting interests the district court has broad discretion to decide what degree of protection is required.” *Id.*

IV. ANALYSIS

The first question the Court must consider is whether allowing Vroom access to highly confidential information would create an unacceptable risk of inadvertent disclosure. Vroom asserts on behalf of Breckenridge that he does not and cannot participate in competitive decisionmaking. Vroom Dec. ¶ 4. Specifically, he is not involved in pricing, product design, patent prosecution, or deciding which brand-name drug products Breckenridge pursues or with whom Breckenridge partners. *Id.* Moreover, the terms of the DCO would bar Vroom from these and other activities during the course of this suit and for one year thereafter. *Id.* ¶ 5. Vroom attests that, apart from approximately 15 days per year, he works either from home or at the office of outside law firms. Also, his computer cannot be accessed by Breckenridge nor vice versa. Moreover, Vroom is apparently the only Litigation Counsel within Breckenridge. *See generally*, Vroom Dec. ¶ 8; Declaration of Liza Walsh at Exhibit A.

Sanofi does not contend that Vroom participates in competitive decisionmaking at Breckenridge. Rather, Sanofi argues that other factors provide good cause for limiting his access to highly confidential information: Breckenridge is a small company; its legal team has only four members; Vroom reports to a general counsel who also has a strategic executive title;

and Breckenridge files generic pharmaceutical applications for itself and others. Joint Letter at 6. Sanofi also refers to text it gleaned from Breckenridge's corporate website suggesting that Vroom's position is part of an in-house litigation team, rather than sole litigation counsel. Sanofi cites no authority in support of these factors, and the Court was unable to locate any.

The weight of Sanofi's assertions, including the generic web-page, must be balanced against Vroom's specific declaration that sets out his discrete function and his separation from the rest of Breckenridge, including its other in-house attorneys.

Under similar circumstances, in *Matsushita Elec. Indus. Co., Ltd. v. United States*, 929 F.2d 1577 (Fed. Cir. 1991), the Federal Circuit reversed a lower court's denial of confidential access to in-house counsel. 929 F.2d at 1580. The *Matsushita* panel reasoned that "to be denied access to confidential information merely because they have regular 'contact' with those who are involved in competitive decisionmaking . . . would disqualify almost all in-house counsel and thus effectively constitute the very per se rule we rejected in *U.S. Steel*." *Id.* (emphasis omitted). Here, Vroom's contact with others within the corporation, regular or not, cannot alone disqualify him.

Likewise, in *Affymatrix, Inc.*, a district court in Delaware found that an entire in-house litigation unit was entitled to access to confidential documents, given procedural safeguards the corporation had put into place to reduce the risk of inadvertent disclosure, including separating the unit's offices and its computer systems and isolating the unit's attorneys from competitive decisionmaking. 2005 WL 1801683, at *2–3. Here, Breckenridge has introduced similar safeguards and Vroom, as a single attorney, arguably poses an even lower risk of inadvertent disclosure.

Sanofi also argues that because Vroom negotiates settlement agreements, granting him access to Sanofi's sensitive financial information would give Breckenridge a competitive advantage in any future settlement negotiation. In response, Breckenridge cites a district court's rejection of this argument on the basis that "settlement of patent cases, usually by licensing, is part of litigation." *Trading Technologies Intern., Inc. v. eSpeed, Inc.*, Civ. No. 04-5312, 2006 WL 1994541, at *2 (N.D. Ill. July 13, 2006). The Court finds this reasoning persuasive. Sanofi's argument would require courts to exclude any attorney that had reviewed an opponent's financial information from participating in settlement negotiations. It is common practice for corporate litigants to exchange such information during a suit and then expect advice from their litigation counsel as to how best to settle their dispute.

Having considered the parties' arguments, the Court finds Vroom's assertions compelling. In short, it is difficult to imagine how Breckenridge might further isolate Vroom in order to reduce the risk of inadvertent disclosure. Whether or not he can be accurately described as part of an "in-house litigation team" as the Breckenridge website states, Vroom has been functionally, geographically, and technologically isolated from his peers. The undersigned finds this is enough. For the foregoing reasons, the Court finds that Vroom does not engage in competitive decisionmaking. Moreover, given the protections Breckenridge has put into effect and the terms to be imposed by the proposed DCO, the Court further finds that the risk of inadvertent disclosure posed by Vroom is minimal.

Having considered the risk of inadvertent disclosure, the Court turns next to an assessment of the harm to Breckenridge if Vroom were denied access. Sanofi contends that Breckenridge has failed to explain why Vroom needs access to the highly confidential documents. Because Sanofi has agreed to disclose to Vroom all but a narrow subset of the most

sensitive materials, any harm to Breckenridge should be minimal. Breckenridge claims, however, that this harm would be significant, given that documents in this category will inform its patent invalidity position. Joint Letter at 3. Indeed, Vroom states in his Declaration that he needs such access to properly advise Breckenridge, to take and defend depositions, work with experts, argue motions, and examine witnesses at trial. Vroom Dec. ¶ 3. The Court also accords weight to the fact that Breckenridge created the position of Litigation Counsel in 2009 and has maintained it for the very purpose being considered here and consistent with the opportunity afforded by the Federal Circuit's decision in *U.S. Steel*. Accordingly, the Court finds that Breckenridge would in fact be harmed if Vroom were denied full access to the confidential documents in this matter, regardless of whether the information at issue is deemed confidential or highly confidential. Because the safeguards put in place by Breckenridge mean that the risk of disclosure is minimal, the Court finds that the harm to Breckenridge clearly outweighs that risk.

Finally, Sanofi attempts to re-couch Breckenridge's request as seeking Vroom's classification as outside counsel when he is in fact in-house. Joint Letter at 4–5. Sanofi contends that this would conflict with the New Jersey Court Rules, the New York Court Rules, and this District's Local Patent Rules, each of which defines in-house counsel. Breckenridge does not, however, dispute that Vroom is in-house counsel and the Court fails to see how this is relevant. The question is whether an in-house attorney under Vroom's circumstances should be permitted access to documents typically limited to outside counsel. Labels aside, the case law recognizes conditions under which this is appropriate, and the undersigned finds that Breckenridge has met these conditions.

V. CONCLUSION

For the reasons set forth above, the Court finds that Vroom should be permitted full access to materials marked confidential and highly confidential under the DCO.

THEREFORE, for the reasons stated above, and for good cause shown,

IT IS on this 25th day of **January, 2016**,

ORDERED that Breckenridge's request that its in-house Litigation Counsel, Robert Vroom, be permitted access to confidential information, including that which is marked "HIGHLY CONFIDENTIAL, OUTSIDE COUNSEL EYES ONLY" under the proposed Discovery Confidentiality Order, is GRANTED; and it is further

ORDERED that Vroom is not to review, store, or access any information designated by Sanofi as OUTSIDE COUNSEL EYES ONLY, while at any Breckenridge facility; and it is further

ORDERED that Breckenridge is to continue to maintain separate computer facilities for Vroom, such that Vroom does not have access to Breckenridge's network drives and Breckenridge does not have access to Vroom's computer; and it is further

ORDERED that Breckenridge is to immediately inform Sanofi if the nature of Vroom's role or facilities change; and it is further

ORDERED that, with the modifications Ordered above, the Court otherwise accepts the limitations to the Discovery Confidentiality Order proposed by Breckenridge; and it is further

ORDERED that within 5 days of the entry of this Order, the parties are to submit a Discovery Confidentiality Order consistent with this decision.

A handwritten signature in black ink, appearing to read "Lois H. Goodman", written over a horizontal line.

LOIS H. GOODMAN
United States Magistrate Judge